

Senate File 362 - Introduced

SENATE FILE 362

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A BILL FOR

1 An Act relating to the use of adult stem cells in this state,
2 including uses relating to the practice of medicine, the
3 practice of pharmacy, and clinical research.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 136E.1 Definitions.

2 As used in this chapter unless the context otherwise
3 requires:

4 1. "*Adult stem cells*" means autologous or allogeneic
5 cellular material including but not limited to stem cells,
6 immune cells, and other types of mature cells that may have
7 been or may be combined with naturally occurring biomaterials
8 or materials approved or cleared for any purpose by the United
9 States food and drug administration or other applicable agency
10 or authority.

11 2. "*Allogeneic*" means originating from the body of another
12 person.

13 3. "*Autologous*" means originating from a person's own body.

14 4. "*Cell or tissue bank*" means a facility that stores adult
15 stem cells or tissue.

16 Sec. 2. NEW SECTION. 136E.2 Practices relating to adult
17 stem cells.

18 1. Notwithstanding any law to the contrary:

19 a. A person licensed to practice medicine pursuant to
20 chapter 148 in this state may extract, process, or administer
21 autologous adult stem cells.

22 b. A person licensed or authorized to administer or assist
23 in the administration of medicine or health care in this state
24 may extract, process, or administer autologous adult stem
25 cells to the extent permitted under the person's license or
26 authorization.

27 c. A person may operate a cell or tissue bank in this state.

28 d. A pharmacy owned or operated in this state, or a
29 pharmacist licensed pursuant to chapter 155A, may compound a
30 drug, medicine, or health product using adult stem cells as an
31 ingredient.

32 e. A person licensed to practice medicine in this state may
33 conduct adult stem cell clinical research for development of
34 therapies and cures consistent with chapter 707C. This chapter
35 shall not be interpreted to limit or prohibit any activity

1 otherwise authorized pursuant to chapter 707C.

2 *f.* A person authorized to conduct adult stem cell clinical
3 research in the state may import into this state any compound
4 or drug containing adult stem cells if the compound or drug is
5 obtained in accordance with the laws of the jurisdiction from
6 which the compound or drug is obtained and the compound or drug
7 is used for the purposes of clinical research.

8 *g.* A person who is authorized to extract, process, or
9 administer autologous adult stem cells under this section
10 may import into this state compounds and drugs used in the
11 administration of such stem cells if the compound or drug is
12 obtained in accordance with the laws of the jurisdiction from
13 which the compound or drug is obtained and the compound or drug
14 is used for administration of autologous adult stem cells to a
15 person in a treatment plan by a person licensed or authorized
16 to extract, process, or administer autologous adult stem cells.

17 2. *a.* The board of medicine, the board of pharmacy, and
18 other appropriate licensing boards established pursuant to
19 chapter 147 shall adopt rules in accordance with this chapter.
20 The rules adopted shall not prohibit the activities authorized
21 in this chapter and shall not impose disciplinary action or
22 civil or criminal penalties against a person for engaging
23 in any activity authorized by this chapter. This paragraph
24 shall not be interpreted to authorize the adoption of rules
25 that absolve a person from civil or criminal liability or
26 disciplinary action otherwise applicable if the person engages
27 in an activity authorized under this chapter but fails to use
28 the reasonable care, skill, or knowledge ordinarily used in
29 rendering medical services under similar circumstances.

30 *b.* The board of medicine, the board of pharmacy, and other
31 appropriate licensing boards may adopt rules to regulate the
32 procedures used to administer adult stem cells in this state.

33 EXPLANATION

34 This bill relates to the use of adult stem cells in the
35 state, including uses relating to the practice of medicine, the

1 practice of pharmacy, and clinical research.

2 The bill defines terms used in the bill and authorizes
3 certain activities relating to adult stem cells. The bill
4 authorizes a person licensed to practice medicine in the state
5 to extract, process, or administer autologous adult stem cells.
6 "Autologous" means originating from the person's own body.
7 The bill also provides that a person licensed or authorized
8 to administer or assist in the administration of medicine or
9 health care in this state may extract, process, or administer
10 autologous adult stem cells to the extent permitted under the
11 person's license or authorization.

12 The bill authorizes all of the following: the operation
13 of a cell or tissue bank in this state; a pharmacy owned or
14 operated in the state or a licensed pharmacist to compound
15 a drug, medicine, or health product using adult stem cells
16 as an ingredient; a person licensed to practice medicine to
17 conduct adult stem cell clinical research for development of
18 therapies and cures consistent with Code chapter 707C (human
19 stem cell research and cloning) while clarifying that the
20 bill is not to be interpreted as limiting or prohibiting
21 any activity authorized under chapter 707C; a person who is
22 authorized to conduct adult stem cell clinical research to
23 import any compound or drug containing adult stem cells if
24 the compound or drug is obtained in accordance with the laws
25 of the originating jurisdiction and is used for clinical
26 research; and a person who is authorized to extract, process,
27 or administer autologous adult stem cells to import compounds
28 and drugs used in the administration of such stem cells if the
29 compound or drug is obtained in accordance with the laws of the
30 originating jurisdiction and the compound or drug is used for
31 administration of autologous adult stem cells to a person in a
32 treatment plan by a person licensed or authorized to extract,
33 process, or administer autologous adult stem cells.

34 The bill directs the board of medicine, the board of
35 pharmacy, and other appropriate licensing boards to adopt rules

1 in accordance with the bill, but provides that the rules shall
2 not prohibit the activities authorized in the bill and shall
3 not impose disciplinary action or civil or criminal penalties
4 against a person for engaging in any activity authorized
5 under the bill. However, the bill is not to be interpreted
6 to authorize the adoption of rules that absolve a person who
7 engages in an activity authorized under the bill from civil or
8 criminal liability or disciplinary action otherwise applicable
9 for failure to use the reasonable care, skill, or knowledge
10 ordinarily used in rendering medical services under similar
11 circumstances. The bill does authorize the board of medicine,
12 the board of pharmacy and other appropriate licensing boards to
13 adopt rules to regulate the procedures used to administer adult
14 stem cells in this state.